

**REMARKS**

Claims 37-58 are pending in the present application. Claims 49-58 were previously withdrawn from consideration as drawn to a non-elected invention. By virtue of this response, claim 37 has been amended. Accordingly, claims 37-48 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

**Rejections under 35 U.S.C. §102****Claims 37-44**

Claims 37-44 stand rejected under 35 U.S.C. §102(b), as allegedly anticipated by U.S. Patent No. 5,984,933 to Yoon ("Yoon"). Applicants disagree with this rejection. However, in order to expedite prosecution, Applicants have amended the current claims. Specifically, independent claim 37, from which the remaining rejected claims depend, has been amended to recite a device for applying a tethered clip assembly, *wherein the tethered clip assembly has a first deployed configuration and a second deployed configuration*, the tethered clip assembly in the first deployed configuration comprising at least two clips separated by a first distance and coupled to a tether, *and wherein when the tethered clip assembly is in its second deployed configuration the tether is under longitudinal tension and the first distance is reduced to a second distance, and wherein the at least two clips are in a closed tissue-piercing position when the tethered clip assembly is in both its first and second deployed configuration*.

Yoon fails to teach or even suggest such a device. For example, Yoon fails to teach or suggest the deployment of a tethered clip assembly that has two deployed configurations, where the clips in both configurations are in a *closed tissue-piercing position*, and wherein when the tethered clip assembly is in its second deployed configuration, *the tether is under longitudinal tension and the first distance is reduced to a second distance*. In fact, such a device would be contrary to, and undermine the very purpose of, the device taught by Yoon.

Specifically, Yoon teaches devices for suturing anatomical tissue using one or more knotting elements carried by a length of suture. Yoon emphasizes that knotting of sutures during procedures is time consuming and sometimes difficult (*see, e.g.*, col. 1, lines 38-53). Yoon further states that it “is extremely important for knotting or tying of sutures to be consistently performed to provide a stitch with controlled, non-slipping tension” and that there is “a great need for improving the tying procedure involved in suturing to permit expedited knotting while also providing consistent, secure knots” (*see, e.g.*, col. 1, lines 53-61). To this end, Yoon describes the use of knotting elements that serve as a “knot for the suture stitch” (*see, e.g.*, col. 10, lines 60-61).

Each knotting element of Yoon is first disposed in an open or suture material-receiving position, but once the element is closed, the suture material is gripped by the knotting element such that the knotting element is in a “fixed position” along the suture material (*see, e.g.*, col. 9 lines 15-19 and 25-29, *see also*, element number 20’, FIGS. 4-7). When the knotting element is in its suture material-receiving position, it is open, not closed, and hence is not penetrating tissue.<sup>1</sup> The knotting elements are imposed into a closed state later, *e.g.*, by an external, conventional instrument, such as a grasper or clamp (*see, e.g.*, element number 39, FIG. 3). Yoon’s method of completing a suture stitch is summarized in a step-by-step fashion in FIGS. 4-7.

Even if Yoon is read to disclose at least two clips in a closed tissue-piercing position (which Applicants contest as detailed in footnote 1), Yoon does not teach or disclose a tethered clip assembly that has two deployed configurations, where both configurations have clips in a *closed, tissue-piercing position* and wherein when the assembly is in the second deployed configuration, the tether is under longitudinal tension and the distance between the closed clips is reduced. Indeed, once the knotting elements of Yoon have been closed, they fix the spacing or length of suture material in place (that is their very purpose). Therefore, it is not possible for the device of Yoon to

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<sup>1</sup> Applicants contend that the knotting elements of Yoon never penetrate tissue, even in their closed position, since such a configuration would cause tissue harm. In addition, the knotting element can only remain in the closed (alleged penetrating) position if locking lip 2241 remains engaged to protrusion 2239 (*see, e.g.*, FIG. 44). If protrusion 2241 penetrates tissue prior to locking into protrusion 2239, then the closed position may be compromised, in which case the knotting element will at any time revert to the open (*i.e.*, non-penetrating) position. Simply put, the knotting elements of Yoon, are for knotting suture material (hence their name) and are incapable of effectively penetrating tissue without substantive harm.

have a tethered clip assembly where a length of tether between the clips is reduced once the knotting elements have been closed. For at least the reason that Yoon fails to teach or describe each and every limitation of the current claims, the rejections under 35 U.S.C. §102 cannot stand.

### **Rejections under 35 U.S.C. §103**

#### Claims 45, 46 and 48

Claims 45, 46 and 48 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yoon, as applied to claim 37 above, in view of U.S. Patent No. 5,524,630 to Crowley ("Crowley"). Applicants disagree with this rejection.

Yoon was discussed in detail above with respect to claim 37, from which claims 45, 46 and 48 depend. Specifically, Applicants described how Yoon fails to teach a device meeting each and every limitation of claim 37. Crowley, which is being relied upon for various visualization features, fails to cure this deficiency. For at least this reason, a *prima facie* case of obviousness with respect to claims 45, 46 and 48 cannot stand.

#### Claim 47

Claim 47 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yoon and Crowley as applied to claim 45 above, in view of U.S. Patent No. 5,766,240 to Johnson ("Johnson"). Applicants disagree with this rejection. Claim 45 was discussed just above, where it was noted that a *prima facie* case of obviousness has not been established. Specifically, Yoon and Crowley fail to render claim 45 obvious for at least the reason that they fail to teach (either alone or in combination) a device meeting each and every limitation of claim 37. Johnson, which is relied upon in support of a viewing element, fails to cure this deficiency. Accordingly, a *prima facie* case of obviousness with respect to claim 47 cannot stand.

### CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

Any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child, or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

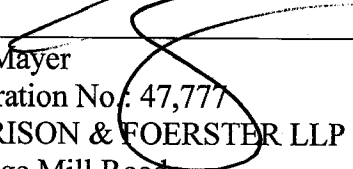
In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the

Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 578492000510.

However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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